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Section 6
510(k) Summary

Submission Date: July 12, 2007 AUG 23 2007

Submitter Information:

Company Name: TraumaCure, Inc.

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Bethesda, MD 20814

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President and Chief Operating Officer
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Device Information:

Trade Name: WoundStat™

Common Name: Wound Dressing

Device Class: Unclassified

Predicate Device: **QuikClot®**
Z-Medica Corporation
K013390

Intended Use: WoundStat™ is intended for use in emergency wound management.

Indications for Use: WoundStat™ is intended for emergency use only as an external temporary traumatic wound treatment to achieve hemostasis for moderate to severe bleeding.

Device Description:

WoundStat™ is a clay-based, granular hemostatic agent that is poured on or into a moderate to severe wound and held in place until it adheres to the wound and hemostasis is achieved. The device is packaged in a foil package and is provided sterile.

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WoundStat has been developed to address an unmet need in battlefield, ballistic, and traumatic injuries. Uncontrolled hemorrhage continues to be a leading cause of death in both the military and in civilian populations under 35 years of age. The primary issue in these deaths is uncontrolled hemorrhage.

Comparison to Predicate Device:

WoundStat™ has the same mechanism of action and intended use as QuikClot®. Both devices use material that has an unusually high adsorptive effect on liquid for the temporary external treatment of traumatic wounds. The rapid adsorption reduces the quantity of liquid present in the wound in a sponge effect, which concentrates coagulation factors and promotes clotting.

WoundStat™ has been tested in pre-clinical models. WoundStat™ has equivalent, if not better, hemostasis results in terms of speed and effectiveness as QuikClot®. In addition, biocompatibility testing was completed. Systemic toxicity, cytotoxicity and intracutaneous studies were performed. The results of these tests demonstrate that WoundStat™ is safe for its intended use.

Conclusion:

WoundStat™ is a safe and effective traumatic wound dressing that is substantially equivalent to the predicate device, QuikClot®. Therefore, WoundStat™ should be regulated by FDA within the same generic type of device that includes the cited predicate and should be cleared for marketing in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2007

TraumaCure, Inc.
% Becker & Associates Consulting, Inc.
Campbell T. Hutton, MSPH
Project Manager
2001 Pennsylvania Avenue, Northwest
Suite 950
Washington, District of Columbia 20006

Re: K071936
Trade/Device Name: WoundStat™
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 14, 2007
Received: August 15, 2007

Dear Campbell T. Hutton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 5
Indications for Use Statement

510(k) Number (if known): K071936

Device Name: WoundStat™

Indications for Use:

WoundStat™ is intended for emergency use only as an external temporary traumatic wound treatment to achieve hemostasis for moderate to severe bleeding.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071936